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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,524	01/15/2004	Jan G. Jaworski	07148-108002	5670

7590 04/20/2007  
FISH & RICHARDSON P.C., P.A.  
60 SOUTH SIXTH STREET  
SUITE 3300  
MINNEAPOLIS, MN 55402

EXAMINER
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KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1656

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/20/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/758,524		JAWORSKI ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Chih-Min Kam		1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2 and 8-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 8-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/16/04</u> .   | 6) <input type="checkbox"/> Other: ____.                          |

### DETAILED ACTION

1. In the preliminary amendment filed January 15, 2004, claims 3-7 and 12-25 have been cancelled. Therefore, claims 1, 2 and 8-11 are examined.

#### *Informalities*

The disclosure is objected to because of the following informalities:

2. The specification recites amino acid sequences (e.g., GNTSSSS) at page 12, lines 19-21, without providing a sequence identifier "SEQ ID NO:". Applicants must comply with the requirements of the sequence rules (37 CFR 1.821-1.825) and provide a copy of sequence listing and CRF containing all the sequences.

#### *Claim Rejections - 35 USC § 101*

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim is drawn to a polypeptide. As written, the claim does not explicitly indicate the hand of man. Insertion of "isolated" or "purified" in connection with a polypeptide is suggested. See MPEP § 2105.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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4. Claims 1, 2 and 8-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 2 and 8-11 are directed to a polypeptide comprising in the amino-terminal to carboxy-terminal direction: a first polypeptide segment having membrane anchoring properties; joined to a second polypeptide segment having a sequence of residues 75-114 of SEQ ID NO:12 or 14; joined to a third polypeptide segment having at least 40% sequence identity to residues 115-506 of SEQ ID NO:4. The specification indicates the present invention provides polypeptide with altered elongase KCS (3-ketoacyl CoA synthase) substrate specificity and/or catalytic activity such as the peptides comprises three polypeptide segments, the amino-terminal first polypeptide segment having membrane anchoring properties, joined to a second polypeptide segment having a sequence of residues 75-114 of SEQ ID NO:12 or 14, followed by a third polypeptide segment having at least 40% sequence identity to the C-terminal 392 amino acids of SEQ ID NO:4 (residues 115-506), examples of such polypeptides have the sequences of SEQ ID NO:12 and 14 (page 3, lines 8-18; page 12, lines 5-9), where residues 115-506 of SEQ ID NO:12 and 14 having >99% sequence identity to the residues 115-506 of SEQ ID NO:4 (see attached sequence match), and the substrate specificity (C22:1/C20:1) of SEQ ID NO:12 or 14 resembles that of the wild-type Bn polypeptide (SEQ ID NO:4, Example 3; Tables 4 and 5). The specification further indicates the Bn G307D polypeptide had a higher elongase activity and produced more C22:1 product than the unmodified wild-type Bn polypeptide (SEQ ID NO:4; Example 4; Table 7). While a species of SEQ ID NO:12 and 14 for altered elongase KCS has

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been disclosed, the specification does not describe a genus of variants for the third polypeptide segment of altered elongase KCS having at least 40% sequence identity to SEQ ID NO:4, and there is no disclosure of any particular structure to function/activity relationship in the disclosed species (i.e., polypeptides having at least 40% sequence identity to SEQ ID NO:4). Without guidance on the correlation of structure to function/activity of the third polypeptide segment of altered elongase KCS, one skilled in the art would not know which residues of the sequence are essential for function/activity. The lack of description on the structure to function/activity relationship of the third polypeptide segment in altered elongase KCS, and the lack of representative species as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

#### ***Conclusion***

5. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Chih-Min Kam, Ph. D.  
Primary Patent Examiner



primary

CHIH-MIN KAM  
PATENT EXAMINER

CMK

September 16, 2006